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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,892	01/03/2001	Leonid A. Yakubov	PANA-0002	1372

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EXAMINER	
PRIEBE, SCOTT DAVID	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/753,892	YAKUBOV, LEONID A.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-68 and 70-79* is/are rejected.

7)☒ Claim(s) *69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit **1633**.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 1/17/06 has been entered.

Claim Objections

Claim 60 is objected to because of the following informalities: The status identifier in claim 60 is incorrect, it was --previously presented-- and is not "new". Appropriate correction is required.

Applicant is advised that should claims 53 or 54 be found allowable, claims 61 or 70, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 61 is simply claim 53 written in independent form, and claim 70 just explicitly recites the limitations that are implicit in claim 54 through its dependence on claim 48.

Claim Rejections - 35 USC § 112

Claim 48-52, 54-57 remain rejected and claims 70-79 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 9/28/04, because the specification, while being enabling for treating an individual exposed to ionizing radiation, does not reasonably provide enablement for treating individuals exposed to other mutagenic stimuli. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's arguments filed 1/17/06 have been fully considered but they are not persuasive. Applicant argues that the evidence and reasoning forming the basis of the rejection are not sufficient evidence that one of skill in the art to doubt Applicant's assertions of enablement. Applicant points out that the claims do not recite a mechanism of action, there is no requirement to describe a mechanism for action of an invention, and that no evidence has been provided that the claimed method will not work.

In response, Applicant is mischaracterizing the grounds of rejection. The guidance in the specification as to what the claimed method is intended to accomplish is based upon the assertion by Applicant in the specification that the method works by repairing DNA damage by

homologous recombination with the exogenous DNA that is administered. The Office has provided substantial evidence that one of skill in the art would not find such an assertion credible. The specification does not disclose any other therapeutic effect of the treatment, so there is no other assertion to challenge. The claims require that the amount of DNA be therapeutically effective, but do not specify what the amount would be effective for. When read in light of the specification, one must assume that the amount is to be effective to repair mutations made by the chemical mutagen. One cannot determine what an effective therapeutic amount would be unless one knows what the therapeutic effect would be; i.e. unless one knows what the invention would be operable for.

Applicant points to ¶ 8 and Exhibit 5 the Declaration of 4/25/03 as evidence that a mouse treated with cyclophosphamide, which is a chemical mutagen, was effectively treated by administration of genomic DNA. However, this evidence showed that the mice recovered from the leukopenia induced by the cytotoxic effects of cyclophosphamide earlier than a mouse that had not been treated with the DNA. Applicant has not indicated where the specification described such a therapeutic effect or mentioned cyclophosphamide exposure, or that the treatment was to be effective for anything other than correction of mutations. As indicated in the grounds of rejection referring to Anderson et al., the cytotoxic effects of cyclophosphamide are thought to be due to blockage of DNA replication caused by inter-strand cross-linking, not by its mutagenic effects. The effect seen in this experiment cannot be extrapolated to all mutagens, since it does not appear that it is the deleterious mutagenic effects of cyclophosphamide being treated by the administered DNA, and one does not know why or how the DNA treatment produced the effect that it did.

Claim Rejections - 35 USC § 102 & 103

Claims 43-53 and 58-60 remain rejected and claims 55-57 and 61-68 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sekiguchi et al., US 3,803,116 for the reasons of record set forth in the Office action of 9/28/04, and the additional reasons set forth in the Office action of 6/16/05. The 2000/2001 Sigma Catalog (page 319) was provided as evidence that at the time of the invention human placental DNA was commercially available. Claims 55-57 were inadvertently omitted from the previous rejection, as is evident from the rejection of claims 58-60 that recite the same additional limitations and the rejection of claims 48-53 relating to the treatment following ionizing radiation exposure.

Applicant's arguments filed 1/17/06 have been fully considered but they are not persuasive. Applicant argues that Sekiguchi does not teach that if human DNA were to be used, that it would be prepared at the same molecular weight or length as the non-human DNA because the lower molecular weight of non-human DNA was to reduce the risk of mutation, and asserts that Sekiguchi teaches away from using human DNA at this lower molecular weight. In response, Sekiguchi teaches (col. 2, lines 3-11) that the reason the DNA was reduced to a MW of 2-5 X 10^5 was because DNA of that size would not genetically transform cells of the patient, and thus avoid potential mutational effects of the foreign DNA. However, this teaching also means that the DNA administered was not intended to recombine with the DNA of the patient in order to produce its restorative effect. Sekiguchi does not teach that larger molecular weight DNA would be expected to have a greater restorative effect. Consequently, Sekiguchi would have

suggested to one of skill in the art that if human DNA were available in sufficient quantity, it would be preferable over foreign DNA to further reduce the risk of mutation, and that the size of the human DNA to be used would be the same as was shown to work with foreign DNA, since there is no reason presented to use any other size of DNA.

Applicant points to the Declaration of 4/25/03 to show that using DNA from the same species works better than using DNA of a different species in promoting survival of an animal after lethal irradiation. However, Applicant does not present any clear argument as to why this experimental result is relevant to the rejection. Also, Wilczok (1965) and Ledoux (1970) (both of record) present extensive examination of this same phenomenon that is exploited by Sekiguchi and is the subject of the experiment described in the declaration. Both found no difference in the effectiveness of homologous vs. heterologous DNA. Second, the fact that applicant may have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985), e.g. because using human DNA to treat a human would further reduce the risk of mutation.

Allowable Subject Matter

Claim 69 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. There is no suggestion in Sekiguchi to use autologous DNA, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633